510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY TEMPLATE

A. 510(k) Number:

k122177

B. Purpose for Submission:

New device

C. Measurand:

Calibrator and quality control materials for urine total protein

D. Type of Test:

Not applicable

E. Applicant:

ELITechGroup

F. Proprietary and Established Names:

ELITech Clinical Systems URINE TOTAL PROTEIN Standard 100 mg/dL

ELITech Clinical Systems URINE CONTROL BI-LEVEL

G. Regulatory Information:

Name	Regulation	Classification	Product Code	Panel
ELITech Clinical Systems Urine Total Protein Standard 100 mg/dL	21 CFR 862.1150, Calibrator	II	JIT	(75) Chem
ELITech Clinical Systems Urine Control Bi-Level	21 CFR 862.1660, Quality control material (assayed and unassayed)	I, reserved	JJX	(75) Chem

H. Intended Use:

1. Intended use(s):

See Indications for use below.

2. Indication(s) for use:
   ELITech Clinical Systems Urine Total Protein Standard 100 mg/dL:
   ELITech Clinical Systems URINE TOTAL PROTEIN Standard 100 mg/dL is intended for the calibration of quantitative ELITech Clinical Systems URINE TOTAL PROTEIN on ELITech Clinical Systems Selectra Pro Series Analyzers.

   ELITech Clinical Systems Urine Control Bi-Level:
   ELITech Clinical Systems URINE CONTROL BI-LEVEL is a set of 2 levels of urine controls used for in vitro diagnostic in the quality control of quantitative ELITech Clinical Systems methods on ELITech Clinical Systems Selectra Pro Series Analyzers.

3. Special conditions for use statement(s):

   The ELITech Clinical Systems Urine Total Protein Standard 100 mg/dL needs to be brought to 18-25°C (room temperature) prior to use.

4. Special instrument requirements:

   For use on the ELITech Selectra Pro Clinical Systems

I. Device Description:

ELITech Clinical Systems Urine Total Protein Standard 100 mg/dL:
ELITech Clinical Systems URINE TOTAL PROTEIN Standard 100 mg/dL is an aqueous solution ready to use containing bovine albumin at a concentration of 100 mg/dL and sodium azide (< 0.1 %).

ELITech Clinical Systems Urine Control Bi-Level:
ELITEch Clinical Systems URINE CONTROL BI-LEVEL is a liquid solution prepared from human urine supplemented with constituents of human and animal origin, chemicals, preservatives and stabilizers for quality control of urine total protein. These controls are prepared exclusively from the human urine where each urine donation is tested individually and found to be negative for HbsAg and to antibodies to HCV and HIV-1/HIV-2 according to FDA-approved methods.

J. Substantial Equivalence Information:

1. Predicate device name(s):
   Horiba ABX Pentra TPU Cal, Biorad Liquicheck Urine Chemistry Control, Level 1 and Level 2

2. Predicate K number(s):

k071779, k020817

3. Comparison with predicate:

ELITech Clinical Systems Urine Total Protein Standard 100 mg/dL

Similarities		
Item	Device k122177, ELITech Clinical Systems Urine Total Protein Standard 100 mg/dL	Predicate k071779, Horiba ABX Pentra TPU Cal
Intended Use	Same	Calibration of urine total protein
Traceability	Same	SRM 927
Levels	Same	Single level

Differences		
Item	Device k122177, ELITech Clinical Systems Urine Total Protein Standard 100 mg/dL	Predicate k071779, Horiba ABX Pentra TPU Cal
Format	Aqueous solution ready to use containing bovine albumin and sodium azide.	A liquid ready to use calibrator based on an aqueous solution containing human serum and sodium azide.
Open vial stability	Stable for 3 months when stored tightly-closed at 2-8 °C.	Once opened, the calibrator is stable for 9 weeks when stored tightly recapped at 2-8°C.

ELITech Clinical Systems Urine Control Bi-Level

Similarities		
Item	Device k122177 ELITech Clinical Systems Urine Control Bi-Level	Predicate k020817, Biorad Liquicheck Urine Chemistry Control, Level 1 and Level 2
Intended Use	Same	Liquicheck Urine Chemistry Control is intended for use as an assayed quality control for urine.
Format	Same	Liquid ready to use, a

Similarities		
Item	Device k122177 ELITech Clinical Systems Urine Control Bi-Level	Predicate k020817, Biorad Liquicheck Urine Chemistry Control, Level 1 and Level 2
		liquid solution prepared from human urine supplemented with constituents of human and animal origin, chemicals, preservatives, and stabilizers.
Levels	Same	2 levels
Stability	Same	Product is stable until the expiration date when stored unopened at 2°-8° C. Open vial stability is 30 days when stored tightly capped at 2°-8° C.

Control material is purchased from a commercial vendor (previously cleared under k020817) with no change to the content and the packaging except the labeling change.

K. Standard/Guidance Document Referenced (if applicable):

None cited.

L. Test Principle:

Not applicable

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

   a. Precision/Reproducibility:

   Not applicable

   b. Linearity/assay reportable range:

   Not applicable.

   c. Traceability, Stability, Expected values (controls, calibrators, or methods):

ELITech Clinical Systems Urine Total Protein Standard 100 mg/dL

i. Traceability: The ELITech Clinical Systems Urine Total Protein Standard 100 mg/dL is traceable to NIST SRM 927.
ii. Stability: Accelerated and real-time testing (on-going) have been conducted using multiple lots of the ELITech Clinical Systems Urine Total Protein Standard 100 mg/dL. In addition, open vial stability has been evaluated. The claimed stability for closed vial shelf life of the ELITech Clinical Systems Urine Total Protein Standard 100 mg/dL is 18 months when stored at 2°-8° C. Open vial stability is 3 months when stored at 2°-8° C. The stability study protocols and the sponsor defined acceptance criteria have been reviewed and found to be acceptable.
iii. Value assignment: Value assignment of the ELITech Clinical Systems Urine Total Protein Standard 100 mg/dL is obtained by assaying the new calibrator sets as unknowns, run in triplicate on one each of the Selectra Pro analyzers. The mean is calculated based upon comparison with an already approved calibrator lot and control materials. The newly assigned values are validated against reference materials, the previous lot of standard, and controls. The value assignment protocols and the sponsor defined acceptance criteria have been reviewed and found to be acceptable.

ELITech Clinical Systems Urine Control Bi-Level

i. Stability: Control material is purchased from a commercial vendor (previously cleared under k020817) with no change to the content and the packaging except the labeling change. The sponsor claims the following stability determined by the provider is: Closed vial 24 months at 2°-8° C, open vial—30 days at 2°-8° C.
ii. Value assignment: Value assignment was determined for urine total protein using multiple analyzer platforms. Value assignment data were collated and an appropriate target value was assigned to each analyte based on the average of the observed values. Ranges were then assigned as +/- 20% of the target. The labeling states that obtained values should fall within the specified range provided on lot-specific value sheets and that laboratories should establish appropriate acceptance criteria when using this product for its intended use.

d. Detection limit:

Not applicable.

e. Analytical specificity:

Not applicable.

f. Assay cut-off:

Not applicable.

2. Comparison studies:

a. Method comparison with predicate device:

Not applicable.

b. Matrix comparison:

Not applicable.

3. Clinical studies:

a. Clinical Sensitivity:

Not applicable.

b. Clinical specificity:

Not applicable.

c. Other clinical supportive data (when a. and b. are not applicable):

Not applicable.

4. Clinical cut-off:

Not applicable.

5. Expected values/Reference range:

Not applicable.

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

1. The submitted information in this premarket notification is complete and supports a substantial equivalence decision.